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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/971,929	10/09/2001	Naoyuki Takano	2185-0577P	2971
	7590 08/06/200 'ART, KOLASCH & E	EXAMINER		
P.O. Box 747			GUDIBANDE, SATYANARAYAN R	
Falls Church, VA 22040-0747			ART UNIT	PAPER NUMBER
			1654	•
			MAIL DATE	DELIVERY MODE
			MAIL DATE	DELIVERY MODE
			08/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	09/971,929	TAKANO ET AL.				
Office Action Summary	Examiner	Art Unit				
	Satyanarayana R. Gudibande	1654				
The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address				
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N.  nely filed  the mailing date of this communication.  D (35 U.S.C. § 133).				
Status						
1)⊠ Responsive to communication(s) filed on 01 Ju	dv 2007					
,—	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>1-5,7,9-14 and 16-21</u> is/are pending in the application.						
4a) Of the above claim(s) 3-5,7,16 and 18 is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
	5)⊠ Claim(s) <u>1, 2, 9-14, 17 and 19-21</u> is/are rejected.					
	7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or	relection requirement.					
Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail D  5) Notice of Informal F					
3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application  6) Other:						

#### **DETAILED ACTION**

#### Election/Restrictions

Applicant's election without traverse of species chitosan trisaccharide and diethylenetriaminepentaacetic acid was acknowledged in the non-final office action dared 10/30/06.

Applicant's amendment to claims in the response filed on 7/1/07 has been acknowledged.

Claims 1-5, 7, 9-14 and 16-21 are pending.

Claims 6, 8 and 15 have been canceled.

Claims 3-5, 7, 16 and 18 are withdrawn from further consideration as being drawn to non-elected species.

Claims 1, 2, 9-14, 17 and 19-21 are examined on the merit.

### Allowable Subject Matter

Claim 19 contains allowable subject matter, i.e., claim is drawn to the elected species chitosan trisaccharide that has been found to be free of art, but contains other species chitosan tetra- to deca-saccharide.

#### Maintained Rejections

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2, 9-14, 17 and 19-21 remain rejected under 35 U.S.C. 102(b) as being anticipated by Paik, et al., J. Nucl. Med. 1983, 1158-1163.

In the instant application, applicants claim a process of producing an amide bond that comprises of reacting a compound having an amino group with a polyaminopolycarboxylic acid anhydride in the presence of the polyaminopolycarboxylic acid.

Applicants state that the cited reference discloses a DTPA anhydride having two anhydride moieties and an acetic acid residue that shows the characteristics absorption bands of anhydride carbonyl and carboxylate carbonyl, however, the reference do not teach that there is DTPA with all the five free acetic aid residues. Applicants argue that the requirement of the instantly of the instantly claimed process are not fulfilled by the presence of a single acetic acid residue on a single DTPA anhydride molecule since the claimed process is conducted in the presence of a polyaminopolycarboxylic acid. Applicants further argue that the cited reference disclose that due to hydrolysis of the anhydride, the pH of the buffer solution was reduced. Applicants state that the cited reference merely teaches that the desired acylation of one anhydride group resulted in the formation of an acetic acid residue but it does not mention that the polyaminopolycarboxylic acid *per se* was present or added to the reaction. Applicants further state that the claimed polyaminopolycarboxylic acid was not added to the reaction in the cited reference and it cannot be said that the reaction was conducted in the presence of the polyaminopolycarboxylic acid.

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Applicant's arguments filed 7/1/07 have been fully considered but they are not persuasive. Applicant's argument that the DTPA anhydride comprises of two anhydride moieties and an acetic acid moiety is correct. However, the claims are drawn to a process of producing an amide bond that comprises of reacting a compound having an amino group with a polyaminopolycarboxylic acid anhydride in the presence of the polyaminopolycarboxylic acid. Applicants argument that the cited reference merely teaches that the desired acylation of one anhydride group resulted in the formation of an acetic acid residue but it does not mention that the polyaminopolycarboxylic acid per se was present or added to the reaction is not persuasive. The claim in the instant application do not recite that polyaminopolycarboxylic acid is added to the reaction mixture. It merely recites reacting a compound having an amino group with a polyaminopolycarboxylic acid anhydride in the presence of the polyaminopolycarboxylic acid. The cited reference of Paik, clearly teaches that the DTPA anhydride hydrolyzes in the presence of water (page 1158, column 2). Therefore, the reaction of amide formation between the compound having an amino group with polyaminopolycarboxylic anhydride occurs in the presence of polyaminopolycarboxylic acid, because of the presence of hydrolyzed product of the DTPA anhydride being present in the reaction mixture.

Therefore, the anticipation rejection as stated in our previous office action dated 3/30/07 is maintained.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana Ř. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Satyanarayana R. Gudibande, Ph.D.

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AMISH GUPTA PRIMARY EXAMINER